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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 311.067/PCT/	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/06799	International filing date *(day/month/year)* 30 MARCH 1999	Priority date *(day/month/year)* 30 MARCH 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant BAYLOR COLLEGE OF MEDICINE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☒ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01 NOVEMBER 1999	11 OCTOBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROBERT A. ZEMAN Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06799

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-61 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the claims:
pages 62-65 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the drawings:
pages 1-50 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [X] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06799

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. _.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/06799

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	10-11, 13-16, 21-24, 27	YES
	Claims	1-9, 12, 17-20, 25-26	NO
Inventive Step (IS)	Claims	27	YES
	Claims	1-26	NO
Industrial Applicability (IA)	Claims	1-27	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-9, 12, 17-20 and 25-26 lacks novelty under PCT Article 33(2) as being anticipated by GEN HOSPITAL CORP. (WO 97/20463).

Claims 1-5 are drawn to conditionally lethal molecules, claim 6 to the nucleic acids encoding said molecules, claims 7-9 to gene therapy vectors encoding said molecules and claims 12, 17-20, 25 and 26 are drawn to methods of using said vectors/molecules to induce apoptosis and tumour reduction. The above cited reference encompasses all the limitations of the aforementioned claims. GEN HOSPITAL CORP. disclose inducible vectors for the delivery of a lethal molecule for the treatment of various maladies by inducing apoptosis in the target cells/tissues (see example 2)

Claims 1-26 lacks an inventive step under PCT Article 33(3) as being obvious over GEN HOSPITAL CORP. (WO 97/20463). GEN HOSPITAL CORP disclose inducible vectors for the delivery of a lethal molecule for the treatment of various maladies by inducing apoptosis in the target cells/tissues (see example 2). While GEN HOSPITAL CORP. do not specifically address the use of inducible lethal molecules to treat prostate hypertrophy or prostate cancer (and indirectly reducing PSA levels), one would used the inducible vectors of GEN HOSPITAL CORP. to treat any malady that involved hyperplastic growth.

Claim 27 the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of using inducibly lethal molecules to determine the biological role of various cell types.

Claims 1-27 meet the criteria set out in PCT Article 33(4) for industrial applicability.

---------- NEW CITATIONS ----------
NONE

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because: the methods recited in claims 12-25 are drawn to treating diseases. This requires *in vivo* application of the vectors recited in claims 1-5. The disclosure is totally silent on what such treatment protocols would entail.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): A01N 37/18, 43/04; C07K 01/00; C12N 5/10, 15/00 and US Cl.: 514/2, 44; 530/350; 536/24.1,435/410

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
ENTRY OF SUBSTITUTE DISCLOSURE DATED 08 NOVEMBER 1999 (PCT/ISA/217) WAS REFUSED

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:
This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-6, drawn to conditionally lethal molecules and nucleic acids encoding said molecules.
Group II, claim(s) 7-9, drawn to gene therapy vectors.
Group III, claim(s) 10, drawn to a transgenic animal.
Group IV, claim(s) 11, drawn to a method of making a transgenic animal.
Group V, claim(s) 12-16, drawn to methods of treating a disease (atherosclerosis).
Group VI, claim(s) 17-20, drawn to methods of inducing tumour regression.
Group VII, claim(s) 21-22, drawn to methods of reducing PSA levels.
Group VIII, claim(s) 23-24, drawn to methods of affecting rate of cell proliferation.
Group IX, claim(s) 25-26, drawn to methods of inducing apoptosis.
Group X, claim(s) 27, drawn to method of determining biological role of a cell type.
The inventions listed as Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first-recited product, conditionally lethal molecules. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.